

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of: Lawrence R. Koh for Reissue of

U. S. Patent No.: 6,015,397

Issued Jan. 18, 2000

For: NEEDLE POINT GUARD SAFETY CAP ASSEMBLY

Assistant Commissioner for Patents
and Trademarks
Washington, D. C. 20231

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INFORMATION DISCLOSURE STATEMENT

Independent patent searches, and patents disclosed through the course of prosecution of the present case in a Patent Cooperation Treaty application, have disclosed patents of which the above-named inventors were not aware at the time of issuance of the above-cited patent, and which suggest that in that issued patent, the inventors had unknowingly not claimed the invention to the full scope to which they were entitled. Additional claims that recite those aspects of the invention are set out in an accompanying preliminary amendment in this reissue application for issued patent No. 6,015,397.

THE OVERALL APPARATUS

The patents so found are hereinafter described, but in brief, it is found that none of this newly discovered prior art nor that previously filed in this case, either show or suggest several key aspects of the invention, namely: (a) a hypodermic syringe and safety shield combination that is pre-fabricated in the factory so as to be shipped in a protective condition; (b) a safety shield adapted for a similarly protective fabrication of that combination in the factory; and (c) a configuration in which the usual protective sheath as typically used to protect a needle for shipment is disposed distally from the safety shield, so that upon removal of that sheath the syringe/safety shield combination is ready for immediate use, that sheath then becoming superfluous since the safety shield itself assumes a needle-protective disposition following such use. The result is that except at the very time the needle is being used for an injection or the like, immediately following removal of a needle-protective sheath, the user is never exposed to a needle in an unprotected condition.

To summarize the patent descriptions given below, in most of the cited patents installation of some kind of needle tip safety shield takes place *in-line* with the needle axis, i.e., the user or

device fabricator who is installing the safety shield exerts an in-line axial force *towards* the tip of the needle, which action is likely to produce a needle stick. As exceptions to that technique, such devices as in the Jenkins and Arcusin et al. patents noted below are installed with the fingers displaced some distance from the needle cannula, but each of these is adapted for "on-site" installation, i.e., at the location of use of the hypodermic needle, and usually immediately before such use, but in the case of Arcusin et al. also after use. With the present invention, and similar to Arcusin et al., only syringe attachment member 150 is moved axially along the needle, and that can likewise be done with the worker's fingers laterally displaced a distance (i.e., the length of the device when extended) away from the needle itself, such that there is much less danger of a needle stick. The principle distinction between Arcusin et al. and the present invention (other than the structure of the safety device itself) is that the present apparatus has both protective and non-protective dispositions, and hence can be factory pre-assembled for shipment in a condition ready for use.

In Jenkins, while the holder 12 (or 15) can be installed onto a hypodermic needle with the user's fingers displaced laterally from that needle, the subsequent installation of the protective cap 16 requires manual inserting of the needle tip into cap 16 and then sliding cap 16 along the needle, a step in which a needle stick can occur. In the present invention, after the syringe attachment member 150 has been placed onto the syringe as noted above, the remainder of the device is rotated approximately 90 degrees to be in line with syringe attachment member 150, the needle is passed through the device (which can likewise be done from the side and during which process the needle tip is within the device), and then cover 110 is similarly rotated into position. Moreover, the rotation of cover 110 is carried out using a sheath 300 that continues to enclose the needle as the device is folded back towards the syringe. There is thus no stage of this installation process in which a worker must move a finger towards, and in line with, an exposed needle tip, since the needle tip is continually covered over by one means or another as soon as syringe attachment member 150 has been installed onto the syringe and the protective structure is rotated into alignment with the needle.

The patents cited below have generally overlooked the issue of safety during the process of installing some particular needle safety shield. Poulson, indeed, suggests that no protection is needed until after the syringe and needle have been used.

"While in use, the hypodermic needle 1 is generally safe from contamination prior to its being inserted into a patient. It is after the needle has been removed that it is potentially hazardous to others." Col. 4, lines 37 - 40.

An important aspect of the present invention that had previously been overlooked, without deceptive intent and which in part prompts the filing of the present reissue application, lies in the structure by which (a) protection against needle sticks is provided at the very outset of associating the device with a hypodermic syringe and needle; and (b) there is formed by the manufacturer a combination of (1) a hypodermic syringe and needle with (2) an installed safety shield device (i.e., unlike the Paudler device, the safety shield device is not manufactured as an integral part of the syringe), that assembled combination then being the "product" that is shipped to a purchaser.

DETAILED PATENT LISTING AND ANALYSIS

U. S. Patent No. 4,867,746 issued Sep. 19, 1989 to Dufresne describes a press-fit needle shield having a "hood shield" disposed at the end of an elongate, flexible body, which hood shield is pushed aside in the course of using the needle and which then snaps back into a protective position following such use. The device is installed by an axial motion towards the syringe that slides an end 17 thereof along the needle then and onto a hub 16 of the syringe.

U. S. Patent No. 4,892,521 issued Jan. 9, 1990 to Laico et al. a protective needle shield that is guided by a pair of resilient guide rods to assume extended (protective) and retracted (unprotected) dispositions, the shield having a hole passing therethrough for acceptance of the needle when in that retracted position.

U. S. Patent No. 5,250,031 issued Oct. 5, 1993 to Kaplan et al. describes a locking needle cover having a retractable cap member connected to the base of the needle by a resilient support that biases the cap member to a protecting position around the needle tip. The needle tip is intended to become extended outwardly from the needle cover upon application of the needle to a patient, the needle cover being forced axially away from the patient against the resilience of the support, both upon and so as to permit, such use, while upon removal of the needle from a patient the resilience of the support moves the needle cover axially outward again so as to cover the needle tip.

U. S. Patent No. 4,911,706 issued Mar. 27, 1990 to Levitt describes a needle cover that is installed by sliding over a hypodermic needle at the tip end and then down to the syringe base, and having a laterally extending spring member which, upon release of a tab, will cause a cap portion of the device axially away from the syringe base so as to cover the needle tip. The cap automatically assumes a position at an angle so as to misalign the needle tip and a hole through the cap, but the cap can then be moved manually so as to align the needle tip with that hole, which permits the needle to pass outwardly through the cap for use. After use, the

cap then automatically becomes aligned at an angle so as again to cover the needle tip.

U. S. Patent No. 5,256,152 issued Oct. 26, 1993 to Marks describes a device similar to that of Dufresne, noted above, except for including retracted and extended positions of its needle shield as well. In addition, the shield device may be moved laterally away from the needle so as to permit unfettered access to a patient for conducting a rapid, "dart-like" injection and withdrawal, and in either case the shield returns to a protecting position after the needle has been used.

U. S. Patent No. 5,584,818 issued Dec. 17, 1996 to Morrison describes a spring-loaded needle safety shield that is initially disposed in a retracted, non-protective position, but upon activation of a release latch the shield moves outwardly along the needle cannula where it can be locked in any desired position, including full extension so as to cover over the needle tip. One-way locking means including a pivot plate then prevent the shield from being moved back up the needle so as to expose the tip.

U. S. Patent No. 5,735,827 issued Apr. 7, 1998 to Adwers et al. describes a shield assembly for a hypodermic syringe having firstly an inner shield that initially has a position proximal (non-protective) to the syringe, but can by one hand be placed into distal (protective) positions along a needle cannula, including a fully extended position that covers the needle tip, and secondly an outer shield that is frictionally and removably positioned over the needle cannula when the inner shield is in its proximal position, thereby to cover over the needle tip before the syringe is used. Following use of the syringe, the inner shield can be released to its most distal, protective position and the outer shield is permanently locked in place over the inner shield and needle cannula so as to preclude further use of the syringe.

U. S. Patent No. 5,549,570 issued Aug. 27, 1996 to Rogalsky et al. describes a protective element for covering the tip of a hypodermic needle by way of a moveable hood having an exposing position and enclosing position, together with a spring that is compressed when the hood is in an exposing position, and expansion of the spring then places the hood in an enclosing position, i.e., so as to cover over the tip of the needle. A pivotal retaining element is rotated in order to release the spring so that it may extend and thereby place the hood in that enclosing position.

U. S. Patent No. 6,159,184 issued Dec. 12, 2000 to Perez et al. differs from the invention and indeed from the other patents cited herein in having a body adapted to enclose an entire syringe or ampule and its associated needle therewithin, together with a shield that is slidably attached to that body so as to permit distal movement thereof, such movement of the shield

following use of the needle then covering over the needle tip.

U. S. Patent No. 5,348,544 issued Sep. 20, 1994 to Sweeney et al. describes a single-handedly actuatable safety shield for needles, including a guard that is slidably movable along the needle cannula from a proximal position wherein the needle tip is exposed to a distal position where the tip of the needle is safety shielded. A collapsible hinged arm connects at a first end to a hub of a syringe, and at an opposite end to the guard, whereby extension of the hinged arm by finger-tip pressure thereon places the guard over the needle tip.

U. S. Patent No. 5,700, 249 issued Dec. 23, 1997 to Jenkins describes (as noted above) a needle tip safety device having a base that connects to a syringe, a cup-like protective cap, and an elongate arm that interconnects the base and cap, that arm having two flexibly interconnected segments that can be folded into an acute relative angle therebetween when the cap is in a non-protecting position proximal to the base, and that are nearly colinear when the cap has been extended distally into a protective position.

UK Patent Application GB 2 283 429 A published 10.05.1995, also by Jenkins, describes essentially the same invention as does Jenkins '249 but describes an additional embodiment thereof having a protective cap that is essentially spherical.

U. S. Patent No. 5,242,417 issued Sep. 7, 1993 to Paudler describes a syringe guard that is manufactured integrally with and forms a part of the syringe itself, and having a needle cover that pivots about an axis orthogonal to the syringe/needle axis, so that once such pivoting is initiated, a spring aids on "snapping" the cover over the needle length so as to surround the needle tip.

U. S. Patent No. 5,312,369 issued May 17, 1999 to Arcusin et al. describes a laterally installed safety hood for hypodermic needles in the form of an elongate hollow box, including inter-spaced U-shaped cross-sectional walls having notches therein for reception of the needle cannula along its length.

U. S. Patent No. 5,300,039 issued Apr. 5, 1994 to Poulsen describes a safety device for a hypodermic syringe having a spring-loaded hollow member disposed about the needle cannula and being held in a non-protecting position proximal to the syringe by a pair of supporting members having stops at distal ends thereof, against which stops the distal end of the hollow member is pressed by the spring, so that upon squeezing together those support members at a point near to the syringe, the stops are caused to move apart and the hollow member is then forced distally along the needle cannula to encompass the tip.

U. S. Patent No. 5,591,133 issued Jan. 7, 1997 to Feuerborn et al. (and owned by one of

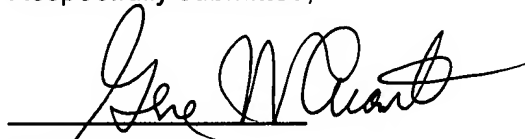
the present inventors) describes a flexing sheath for hypodermic needles wherein the shield initially encloses the hypodermic needle, in a "safe position," but which has mutually hinged sleeve portions so that an axial force thereon will move the distal ends of the sleeve towards the syringe, thereby to expose the needle for use. After use, the elasticity of those hinges automatically returns the distal-most portions of the sleeve outwardly so as again to shield the needle tip.

European Patent Application 0 344 606 A2 in the name of Habley Medical Technology Corporation, published 06.12.89, describes a collapsible needle cover having a needle-enclosing sheath and a pair of mutually hinged needle cover segments which, rather than providing means for moving a separate sheath outwardly to encompass a needle tip as in Feuerborn et al., themselves provide the needle-encompassing function when so extended.

THE NEEDLE TIP COVER SUBCOMBINTAION

Despite the cancellation of claims 12 and 13 of the original application after they were rejected on references, it is believed that many aspects of the needle tip cover as a subcombination are properly patentable. Accordingly, new Claims 34 through 60 have been submitted in the accompanying Proposed Amendment.

Respectfully submitted,



Gene W. Arant
Reissue Attorney for Lawrence R. Koh
Reg. No. 17,936

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P.O Box 0269
Lincoln City, OR 97367
Phone: (541) 764-3300
FAX: (541) 764-3308
email: gwapat@wcn.net